REMARKS/ARGUMENTS

Claims 1-20 are currently pending in this application. It is respectfully submitted that the following remarks present no new issues or new matter and place this case in condition for allowance. Reconsideration of the application in view of the following remarks is respectfully requested.

I. Rejection of Claims 1-20 under 35 U.S.C. §102 (e)

Claims 1-20 are rejected under 35 U.S.C. §102 (e) as being anticipated by Li et al. (US 2005/00640304). The Li publication claims priority to a provisional application filed on June 16, 2003.

In response applicants are submitting a declaration under 37 C.F.R. § 1.131 to antedate the effective filing date of Li. The declaration provides evidence that applicants' tablet composition comprising a sparingly soluble to insoluble drug, i.e. clarithromycin, and at least one polymer having a viscosity less than 50 cps, i.e. hydroxypropylmethyl cellulose 2910 viscosity E5LV, was conceived and reduced to practice before the effective filing date of Li. Applicants conceived and reduced to practice a composition comprising clarithromycin, hydroxypropylmethyl cellulose 2910 E5LV (38.71% composition by weight) and hydroxypropylmethyl cellulose 2910 E15LV (16.47% composition by weight). The viscosities of hydroxypropylmethyl cellulose 2910 E5LV and hydroxypropylmethyl cellulose 2910 E15LV are 4-6 cps and 12-18 cps, respectively (see attached specification for Methocel products from Dow Excipients).

For the reasons set forth above, applicants submit that the rejection of Claims 1-20 under 35 U.S.C. § 102 (e) is rendered moot and withdrawal of this ground of rejection is respectfully requested.

II. Rejection of Claims 1, 2, and 5-20 under 35 U.S.C. §103 (a)

Claims 1, 2, and 5-20 are rejected under 35 U.S.C. §103 (a) as being obvious over Hussain et al. (US 7,037,523).

Hussain discloses a controlled release pharmaceutical composition comprising an acid labile, poorly water insoluble drug, a *water insoluble polymer* and an optimizing agent (abstract and column 4, lines 30-32). Hussain discloses that the water insoluble polymers useful in the invention are water insoluble cellulosic derivatives (i. e. ethyl cellulose), polyvinyl chloride, and amino alkyl methacrylates (column 5, lines 39-42). The optimizing agents useful in the invention are lactose, dicalcium phosphate, calcium phosphate, polymethacrylates, and cationic polymers with dimethyl aminoethyl ammonium functional groups. (column 6, lines 13-18). Hussain does not disclose the use of *hydrophilic polymers* as claimed by applicants. Further, Hussain does

not disclose the use of hydrophilic polymers having a viscosity of less than 50 cps as claimed by applicants.

Hussain points out many disadvantages of the use of hydrophilic water-soluble polymers. Hussain states compositions based on hydrophilic water-soluble polymers commonly exhibit an initial "burst effect" which causes non-linear release rate of a drug (column 2, lines 37-39). Further, Hussain states polymers such as hydroxypropylmethyl cellulose can be hydrated at low pH levels to form a viscous gel layer that controls drug release, and during drug release at high pH levels, the tablets become smaller and smaller due to polymer erosion which affects the dissolution rate (column 2, lines 40-46). In addition, Hussain states the processing of hydrophilic water-soluble polymers such as hydroxypropylmethyl cellulose is difficult and hard to control (column 3, lines 47-49). One skilled in the art would conclude from these statements that there is *no reasonable expectation of success* when hydrophilic water soluble polymers are used, and as a result there is no motivation for one skilled to modify Hussain.

The Office Action states that it would have been obvious to use methyl cellulose in place of ethyl cellulose in view of the close structural similarity. While methyl cellulose and ethyl cellulose are classified as "celluloses", each has very different physical properties. Ethyl cellulose is *insoluble* in water while methyl cellulose swells in cold water and produces a clear to opalescent viscous, colloidal suspension (*Handbook of Pharmaceutical Excipients*, American Pharmaceutical Association, 1986). One skilled in the art would conclude that the properties of methyl cellulose and ethyl cellulose are so dissimilar, that one cannot be used interchangeably with the other. Therefore, there is no motivation to modify Hussain for the reasons stated in the Office Action.

For the reasons set forth above, Applicants respectfully submit that the Examiner has not established a *prima facie* case of obviousness for Claims 1,2 and 5-20 under 35 U.S.C. 103 (a) and withdrawal of this ground of rejection is respectfully requested.

III. Rejection of Claims 3 and 4 under 35 U.S.C. §103 (a)

Claims 3 and 4 are rejected under 35 U.S.C. §103 (a) as being obvious over Hussain et al. (US 7,037,523) in view of Al-Razzak et al. (US 6,010,718).

Hussain has been discussed above in the rejection of Claims 1, 2, and 5-20 under 35 U.S.C. §103 (a).

Al-Razzak discloses a pharmaceutical composition for extended release of an erythromycin derivative (abstract). While Al-Razzak discloses that the pharmaceutically acceptable polymer is a water-soluble hydrophilic polymer, the preferred polymer is low viscosity hdroxypropymethyl cellulose with a viscosity ranging from about 50 cps to about 200 cps with the most preferred viscosity of about 100 cps (column 3, line 65 continuing to column 4, line 24).

Al-Razzak fails to disclose applicants' claimed composition comprising, *inter alia*, hydrophilic polymers having a viscosity less than about 50 cps.

The motivation or suggestion to combine references in the manner suggested by the Examiner must come from the applied references. See MPEP 2143.01. There is no disclosure, direction, or motivation in either Hussain or Al-Razzak to suggest the combination asserted by the Office Action. One of ordinary skill would conclude that Hussain has provided a successful, working formulation of acid labile, poorly soluble drugs comprising a water *insoluble* polymer. One of ordinary skill would also conclude that Al-Razzak has provided a successful, working formulation for erythromycin derivatives comprising a water soluble hydrophilic polymer having a *viscosity from about 50 cps to about 200 cps.* As water insoluble polymers and hydrophilic polymers are separate families of polymers, there is no motivation within Hussain or Al-Razzak for one skilled to combine Al-Razzak with Hussain in the manner suggested by the Office Action.

Assuming arguendo, even if motivation to combine the references in the manner suggested by the Office Action did exist in the applied references, the resultant combination still would not disclose applicants' claimed invention. One skilled in the art would draw from the proposed combination of Al-Razzak with Hussain, a extended release antibiotic composition comprising a hydrophilic polymer such as hydroxypropylmethyl cellulose having a viscosity from about 50 cps to about 200 cps.

For the reasons set forth above, Applicants respectfully submit that the Examiner has not established a *prima facie* case of obviousness for Claims 3 and 4 under 35 U.S.C. 103 (a) and withdrawal of this ground of rejection is respectfully requested.

In view of the above, it is respectfully submitted that all of the claims are in condition for allowance, and a Notice of Allowance is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

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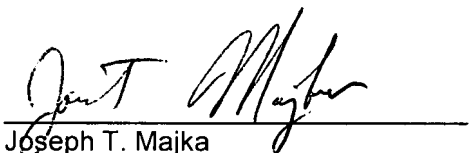

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